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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,879	03/30/2001	Jerry L. Kermicle	WIS4987P0081US	6744
32116	7590	02/24/2005	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/821,879	<b>Applicant(s)</b> KERMICLE ET AL.	
	<b>Examiner</b> David T. Fox	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-17,21-35,39-50,59-68 and 73-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 81 is/are allowed.
- 6) ☒ Claim(s) 1-5,9-17,21-35,39-50,59-68,73-80 and 82-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments of 06 December 2004 have obviated the objections to the specification and claims, and the new matter rejection, set forth in the last Office action.

Claims 9-17, 21-26, 39-50, 59-68 and 73-80 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 3 of the last Office action.

Claims 9-17, 21-26, 39-50, 59-68 and 73-80 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to maize plants containing the TCB trait from maize line W22-TCB (ATCC No. PTA-1601) and methods of using them, does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait or gene cluster, any Tcb locus, any "modifier gene", any "pollen effect" gene, any "silk effect" gene, or methods of using them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 5 of the last Office action.

Claims 1-5, 9-17, 21-35, 39-50, 59-66, 74, 77 and 79 remain, and newly submitted claims 82 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Kermicle et al (1990), as stated on page 7 of the last Office action for claims 1-5, 9-17, 21-35, 39-50, 59-66, 69-72 [sic], 74, 77 and 79.

Claims 1-5, 9-17, 21-35, 39-50, 59-68, 74-77 and 79-80 remain, and newly submitted claims 82-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kermicle et al (1990) taken with Nelson, as stated on page 9 of the last Office action for claims 1-5, 9-17, 21-35, 39-50, 59-68, 69-72 [sic], 74-77 and 79-80.

Claims 73, 78 and 81 are deemed free of the prior art, as stated on page 10 of the last Office action for claims 73 and 78.

Claim 81 is allowed.

Applicant's arguments filed 06 December 2004, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the disclosure of the location of the gene cluster conferring the TCB trait, the dominant expression of the gene cluster, the location of the *Tcb* locus, the approximate location of the modifier gene, molecular markers for use in identifying the gene cluster, and the deposited W22-TCB plant which is the source of the gene cluster.

The Examiner maintains that insufficient information has been provided to describe the broad genus of the claims. The rejected claims are not limited to W22-TCB as the source of the gene cluster. The Examiner has previously indicated that the alleged disclosure of a putative location of desired genes in W22-TCB, particularly when

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said location has been determined by molecular markers, is insufficient to provide any reliable information about the location of said putative gene cluster in plants which do not have W22-TCB in their pedigree. The Examiner reiterates his position that the specification is confusing with regard to the actual location of the modifier gene(s) and the actual composition of the gene cluster or *Tcb* locus. Finally, the Examiner reiterates his position that a disclosure of a method for producing a product does not reduce to practice the product itself, per *Bayer v. Housey*. See pages 4-5 of the last Office action.

Applicant urges that the enablement rejection is improper, given the disclosure of the location of the gene cluster conferring the TCB trait, the dominant expression of the gene cluster, the location of the *Tcb* locus, the approximate location of the modifier gene, molecular markers for use in identifying the gene cluster, and the deposited W22-TCB plant which is the source of the gene cluster.

The Examiner maintains that the alleged information provided by the specification is inconclusive and insufficient to enable the broadly claimed invention, particularly in view of the evidence of unpredictability provided by the Examiner in the form of scientific reasoning and published journal articles. See pages 6-7 of the last Office action.

Applicant urges that the anticipation rejection is improper, given the demonstration in the Kermicle Declaration of 15 April 2004 that the TIC trait taught by Kermicle et al (1990) is not the same as the gene cluster conferring the TCB trait instantly claimed, as also set forth in Table A on page 22 of the Response of 06 December 2004. Applicant further argues that the confusion on page 17 of the

specification, regarding the assignment of the TIC-CP1 gene to the instantly claimed TCB trait and *Tcb* locus, was due to a mere typographical error.

The Examiner maintains that an allegation of typographical error is not probative. If an error in the instant specification has been made, a continuation-in-part application should be filed, which corrects the error. The excerpted portion of Figure 4A of the specification does not negate the Examiner's interpretation of the instant specification. Accordingly, the Examiner maintains that the plants taught by Kermicle et al (1990) contain the same genetic components as the instantly claimed plants. It is immaterial that Kermicle et al (1990) did not recognize that the "undefined functions" of the prior art plants (as set forth in Figure 4A of the instant specification) encompassed the "silk effect function" and "pollen effect function" and "at least one modifier gene" of the instantly claimed TCB trait conferred by a *Tcb* locus (as set forth in Figure 4B). The instant application appears to merely be a further characterization of plants containing the same genetic locus as the prior art plants. See pages 8-9 of the last Office action.

See also *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202, (Fed. Cir. 2002), which teaches that newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable.

It is also noted that the claims are not limited to an isolated gene cluster encoding a TCB trait which excludes the presence of the TIC-CP1 genetic factor, or plants containing said isolated cluster but not containing the TIC-CP1 genetic factor. Instead, the claims are drawn to plants which *comprise* a gene cluster encoding the TCB trait. See page 24 of the Response of 06 December 2004, first full paragraph,

where Applicant admits that the W22-TCB plant, the source of the instant gene cluster conferring the TCB trait, also contains the genetic factor TIC-CP1.

Thus, even if Applicant were successful in demonstrating that the gene cluster encoding the TCB trait is different from the gene cluster found in the prior art, it remains that claims drawn to plants which merely comprise a gene cluster encoding the TCB trait may still be anticipated by the prior art plants, given the open language of the claims. Furthermore, it is not clear that sufficient basis occurs in the instant specification for any exclusionary language, and the Examiner is not suggesting the submission of such claims in an amendment after final rejection. If Applicant has obtained actual plants which clearly do not contain the TIC-CP1 genetic factor, claims limited to these particular plants may be deemed free of the prior art. Such plants should be deposited in accordance with 37 CFR 1.801-1.809 in order to satisfy 35 USC 112, first paragraph.

Applicant urges that the obviousness rejection is improper, given the failure of the primary reference to teach or suggest the use of the particularly claimed molecular markers to obtain the claimed plants containing a gene cluster encoding the TCB trait, the failure of the primary reference to teach the constituents of the instantly claimed plants used in the instantly claimed methods, and the failure of the secondary reference to cure the deficiencies of the primary reference.

The Examiner maintains that the primary reference does indeed teach the same plants as those recited in the instantly claimed product claims, as stated above.

Furthermore, the instantly claimed process claims which are included in this rejection

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are merely drawn to methods of crossing the resultant plants, wherein the molecular marker-based method of obtaining the plants would not confer a unique property to the resultant plants, as stated above. Claims which are limited to methods for identifying plants via the use of particular molecular markers, i.e. claims 73 and 78, are not included in the rejection.

Furthermore, Kermicle et al teach plants which inherently contain the gene cluster encoding the TCB locus, as discussed above. Nelson et al teach the crossing of such plants to produce hybrids and other derivatives. See *Novitski* cited on page 10 of the last Office action.

It is further noted that many of the rejected claims are not limited to any molecular marker (see claim 59) or any particular source of the TCB trait (see claims 9-17, 21-26, 39-50, 59-68 and 73-80). In contrast, Applicant only demonstrates plants derived from W22-TCB which can be used as the source of the TCB trait, or the use of the molecular markers umc1117 and bnlg490 in Figure 3B to identify the presence of the gene cluster encoding the TCB trait.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 18, 2004

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

